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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,916	02/11/2002	Thomas Ritter	219148US0CONT	9410

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EXAMINER	
MARVICH, MARIA	

ART UNIT	PAPER NUMBER
1636	17

DATE MAILED: 08/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 10/068,916	Applicant(s) RITTER ET AL.	
	Examiner Maria B Marvich, PhD	Art Unit 1636	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 July 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *18-58*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☒ Other: *See Continuation Sheet*

TERRY MCKELVEY
PRIMARY EXAMINER

Continuation of 3. Applicant's reply has overcome the following rejection(s): The rejection of claims 18-27 under 35 U.S.C. 102(b) as. being anticipated by Georges et al. is withdrawn. The rejection of claims 21, 23-27 and 35-41 under 35 U.S.C 112, second paragraph, are wtihdrawn in light of amendment to claims. Objection to claims 35 and 37-41 have been overcome by the proposed amendment such that the cited claims are in proper dependent form.

Continuation of 5. does NOT place the application in condition for allowance because: applicant's amendment does not overcome the rejections of claims under 112, first paragraph. .

Continuation of 10. Other: Newly added claims 54-58 are duplicates of newly added claims 49-53.

On pages 8-12 of the amendment filed 7/11/03, Paper No.15, applicant traverses the rejection of Claims 18-48 under 35 U.S.C. 112, first paragraph. Applicant argues that in contrast to alleged basis of the rejection the specification does provide a utility for the use of modified T cells. Applicant cites the MPEP 2164.07(I)(B) which states that the Examiner has the initial burden upon challenging an asserted utility. Applicant argues that the specification teaches a utility for use of the modified T cells aside from gene therapy protocols refering to pages 21-23 of the instant application. Applicant also argues that patentability guidelines should not be confused with FDA safety and efficacy guidelines as the basis for approval. In re Brana is cited. It is argued that a need for further research and development for actual clinical protocols to be developed should not impact the patentability of the invention. As support for disclosure of enabling teachings in the specification, the applicant points out, referring to MPEP 2164.01, that the patent need not teach what is well known in the art.

Applicant's arguments filed 7/11/03 have been fully considered but they are not persuasive. The arguments in Paper No. 15 relating to the utility of the invention find no basis in the rejection under 112, first paragraph as stated in Paper No. 6 and maintained in Paper No. 13. The rejection of claims 18-48, for lack of enablement of the claimed invention, does not relate to the utility of the invention. That the modified T-cells and methods for making the cells are included in the rejection stems from their sole disclosed use in the gene therapy protocols of claims 35-48. Referenced pages 21-23 meant to provide teachings that the modified T cells have use for applications other than for treating patients undergoing allogenic grafts, describe in vitro assays are disclosed for the assay of the inhibition of the proliferation of T cells on page 21 and for the inhibition of Interfreron production on page 22 and in comparison of gene transfer methods. The in vitro "experiments help to characterize the therapeutic cells distinctly", Therefore, the referenced passages relate to establishing a method for using the modified T-cells in vivo. Furthermore, the rejection under 112 first paragraph does not reference FDA guidelines as FDA approval is not a requirement for patentabillity. However, under 35 USC 112, first paragraph, the specification should teach one how to make and use the invention. As filed, the specification does not teach one how to use the invention. Arguments pertaining to the unpredictability of the art and the state of the art for use of retrovirally transduced cells for gene therapy were presented in the Office action filed 7/19/02, Paper No. 6.

The Declaration of Dr. Ritter, Paper No. 3, filed on 5/07/02 under 37 CFR 1.131 has been previously considered in the office action filed 3/11/03, Paper No. 13.